UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, *ex rel.* **JAMES ALLEN,** *Plaintiff,* v. **GUIDANT LLC, formerly doing business as GUIDANT CORPORATION, GUIDANT SALES LLC, formerly doing business as GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., and BOSTON SCIENTIFIC CORPORATION,** *Defendants.*	Civ. No.: 11-cv-22 (DWF/AJB)

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

Rules

PRELIMINARY STATEMENT

Relator James Allen ("Relator") submits this Memorandum of Law in opposition to the Defendants' motion to dismiss his Amended Complaint in this False Claims Act ("FCA") action. As detailed herein, and contrary to the Defendants' assertions, this Court has subject matter jurisdiction over Relator's FCA claims. Relator is "an original source" of the allegations set forth in his Amended Complaint. More specifically, Relator has direct and independent knowledge of the "true state of facts" concerning the defective nature of the Defendants' device (Prizm 2 DR defibrillators manufactured after April 16, 2002 ("Prizm devices")) and the Defendants' efforts to conceal the truth about the defective nature of those devices from Relator, the public at large, and the United States Government.

Moreover, Relator has adequately set forth his FCA claims with the particularity required under the law. The Amended Complaint sets forth an extensive fraudulent scheme perpetrated by the Defendants with respect to the Prizm devices manufactured after April 16, 2002. The allegations in the Amended Complaint provide sufficient notice to the Defendants such that they can fully respond. Furthermore, Relator cannot, as Defendants suggest, be required to set forth in exquisite detail every potential fact concerning the fraudulent scheme because certain elements are within the exclusive knowledge and control of the

Defendants. Under well-settled law, these additional details can, and will, be established during discovery in this matter.

Lastly, Defendants' claims that the United States' Complaint in Intervention supersedes the Amended Complaint and bars Relator from proceeding with his FCA claims is wholly unsupported by law. Under the law, a private relator has a right to continue as a party to an FCA action unless that case falls within one of the specific limitations set forth in the statute. None of those limitations is applicable to this case. Additionally, the Government is pursuing claims which are related but distinct from than those being pursued by Relator in his Amended Complaint. Accordingly, the Government's Complaint in Intervention has no effect on Relator's ability to pursue his FCA claims in this action.

BACKGROUND

The Court is respectfully referred to the Affidavit of James Allen, sworn to December 21, 2011, the Declaration of Dennis R. McCoy, dated December 21, 2011, and the exhibits to said documents for a full recitation of the relevant background of this matter.

Relator is a decorated Marine Corps veteran who honorably served in Vietnam from 1966-68, earning three Purple Hearts. Relator has a unique perspective on the health and medical issues facing veterans. For his own part, Relator has, since the late 1980s, experienced serious medical issues involving his

heart. Relator suffered his first heart attack in 1989 and a second heart attack in 1995 before undergoing quadruple by-pass surgery in 1999. On August 23, 2002, Relator suffered a potentially fatal arrhythmia while in his bed, and was only saved by the actions of his wife (who commenced CPR) and first responders who rushed Relator to the hospital. Shortly thereafter, on August 27, 2002, Relator was implanted with a Prizm 2DR defibrillator which, according to company records, was manufactured at Guidant's Ireland Facility on June 13, 2002. And, that began Relator's personal saga involving the Defendants herein and a defective device that proved to be as dangerous as the Relator's underlying heart condition.

In particular, the Prizm device malfunctioned for the first time on December 2, 2002. The device misread Relator's normal heart rhythm as a potentially fatal event and sent seven shocks of up to 750 volts into his heart. This "storm shocking" of his heart rendered Relator unconscious in the street, where he was found by a bus driver who called an ambulance to transport Relator to the hospital. A second malfunction of the device occurred in 2003, when it again improperly "storm shocked" the Relator's heart causing him to fall down a flight of stairs.

Relator's physicians were unable to explain the reason for the repeated malfunctions. However, Realtor, concerned for his own health and safety, began looking into the Prizm devices on his own. In early 2004, Relator located an

adverse event report indicating certain electrical problems with Prizm 2 DR devices manufactured in 2002. Fearing that his device was among those affected, Relator directly contacted the Guidant representative identified in the adverse event report, Guidant's Richard Roy. After many refusals by the company, Relator finally was able to speak to Mr. Roy, who assured him that his device was not affected by the issues identified in the adverse event report because Relator's device was manufactured after FDA approved changes to the device which corrected the problem.

However, having experienced two potentially fatal malfunctions with his own device, Relator was not convinced by Roy's/Guidant's representations. Thereafter, in 2005, more reports of failures of Guidant's devices began to surface. As with the initial adverse event, though, these reports (including New York Times news articles and an FDA news release) addressed Prizm devices manufactured before April 16, 2002. It was at this point that Relator decided he needed to have the Prizm device removed from his chest and replaced by a different device from another company. At the same time, and again after being initially stonewalled by Guidant, Relator was communicating directly with Daniel J. Tich, Manager, the Product Performance Communications, Reliability Assurance for Guidant Corporation, regarding the Prizm devices.

Meanwhile, Relator had scheduled surgery to have the Prizm device replaced. Unbelievably, and without any justification whatsoever, a Guidant Salesman, James Davis, contacted Relator's physician and told him that Relator's device should not be replaced, that Relator's insurance would not pay for the surgery, and that Relator would claim bankruptcy and not pay his medical bills. Relator eventually had the surgery and had the Prizm device replaced, but only after much difficulty and effort and with a different doctor than the one Guidant had poisoned against him.

Throughout this process, despite two malfunctions and despite his surgery, Guidant never reported any adverse events relating to his Prizm device.

Relator's personal experiences, both with the defective device and Guidant's deceptive and underhanded behavior, convinced him that Guidant was not being truthful about the extent of the problems with the Prizm devices, in particular those manufactured after April 16, 2002 (when Guidant falsely claimed it had made FDA approved modifications to resolve any issues with the devices). By January 2006, Realtor had confirmed his suspicions and, through his own review of non-publicly disclosed documents, discovered that the 11,000 plus Prizm 2 DR devices manufactured after April 2002 had a significant failure rate. Relator provided a summary of his information to the FDA on February 2, 2006 in the form of a 27-page written submission. Based on that submission, on February 7, 2006, the

FDA issued an adverse event report. This was the first disclosure of issues relating to devices manufactured after April 2002.

On March 3, 2006, Relator filed a personal civil action against the Defendants in New York State Supreme Court, Erie County (that action was subsequently transferred and joined with Multi-District Litigation pending in this Court – which was later settled). On July 10, 2008, Relator filed his original FCA complaint. That complaint remained under seal at the request of the Government, until March 29, 2010. Relator filed his Amended Complaint on July 22, 2010. The Government then filed its Complaint in Intervention on January 27, 2011.

ARGUMENT

POINT I

THE PUBLIC DISCLOSURE BAR DOES NOT APPLY TO RELATOR'S CLAIMS IN THIS ACTION.

The purpose of the FCA's "public disclosure bar" was articulated by the Eighth Circuit in *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509,1511 (8th Cir. 1994), in which the court stated: "The Act's jurisdictional scheme is designed to promote private citizen involvement in exposing fraud against the government, while at the same time prevent parasitic suits by opportunistic late-comers who add nothing to the exposure of the fraud." Contrary to the Defendants' assertions, this action is not a "parasitic suit." Relator is not an "opportunistic late-comer" who simply stumbled upon a previously filed lawsuit

and reframed it as an FCA complaint. Rather, as discussed herein, Relator is "an original source" of the allegations set forth in the Amended Complaint. Relator had the dubious honor of having his very life put in jeopardy by the Defendants' actions and omissions. He has first-hand knowledge of the fact that Ventak PRIZM 2 DR 1861 defibrillators manufactured after April 2002 were defective and potentially deadly, notwithstanding that Defendants continually claimed that these devices were free from defects – thereby causing the submission of false claims to the government for implantation of these knowingly defective devices into Medicare and Veterans Administration recipients. Moreover, Relator disclosed his knowledge and information to the government prior to commencing this, or any other, action.

The limitation on subject-matter jurisdiction invoked by the Defendants in this case was enacted as part of the False Claims Amendments Act of 1986 (Pub. L. No. 99-562, 100 Stat. 3153, 3157 (1986)). "The 1986 amendments were an avowed attempt to reinvigorate the False Claims Act after a 1943 amendment and judicial decisions interpreting the 1943 amendment had emasculated the 1863 law." *United States ex rel. Minnesota Assoc. of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1041 (8th Cir. 2002). "The goals of the 1986 Amendments Act were (1) to encourage those with information about fraud against the government to bring it into the public domain; (2) to discourage parasitic qui

tam actions by persons simply taking advantage of information already in the public domain; and (3) to assist and prod the government into taking action on information that it was being defrauded." *Id.* at 1042.

Thus, the so-called "public disclosure bar" at issue in this case, 31 USC § 3730(e)(4), provides:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has provided the information to the government before filing an action under this section which is based on the information.

To determine whether the jurisdictional bar applies, a court must answer three questions: "(1) Have allegations made by the relator been 'publicly disclosed' before the qui tam suit was brought? (2) If so, is the qui tam suit 'based upon' the public disclosure? and (3) If so, was the relator an 'original source' of the information on which the allegations were based? Jurisdiction exists only if the answer to one of the first two questions is 'no' or the answer to the third question is 'yes.' The original source inquiry, in turn, has three parts; the relator's knowledge

of the information must be (1) direct and (2) independent, and (3) the relator must have voluntarily provided the information to the Government before filing suit." *Minnesota Assoc. of Nurse Anesthetists*, 276 F.3d at 1042-43.

With respect to the original source inquiry, the Eighth Circuit has defined what is meant by both direct and independent knowledge. As stated by the court in *United States ex rel. Cox v. General Dynamics Armament & Tech. Prods.*, 2010 U.S. Dist. LEXIS 1608, 21-22, 07CV3264 (D. Neb. Jan. 6, 2010):

> The Eighth Circuit has interpreted 'independent knowledge' to mean 'knowledge that is not derived from the public disclosure.' [*Minnesota Assoc. of Nurse Anesthetists*], at 1048. See also *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995) ("'Independent knowledge' has been consistently defined as knowledge that is not dependent on public disclosure.") (citing *Stinson, Lyons, Gerlin & Bustamante*, 944 F.2d at 1160). The meaning of "direct knowledge" is less clearly defined, but the term connotes the "absence of an intervening agency" in the relator's acquisition of the knowledge. *See Minnesota Ass'n of Nurse Anesthetists*, 276 F.3d at 1048. A relator is said to have direct knowledge of fraud when he "saw [it] with his own eyes." *Barth*, 44 F.3d at 703 (quoting *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 656, 304 U.S. App. D.C. 347 (D.C. Cir. 1994)). The direct knowledge requirement was intended to avoid parasitic lawsuits by 'disinterested outsider[s]' who 'simply stumble across an interesting court file.' *Id.* (quoting *United States ex rel. Stinson, Lyons, Gerlin & Bustamante v. Provident Life & Accident Ins. Co.*, 721 F.Supp. 1247, 1258 (S.D. Fla.1989)).

See also Minnesota Assoc. of Nurse Anesthetists, 276 F.3d at 1048-49 (stating that "direct knowledge" means "marked by absence of an intervening agency, instrumentality or influence: immediate" or "unmediated by anything but [the plaintiff's] own labor ... which reflects the congressional intent to avoid parasitical suits in which the plaintiff contributed nothing").

"[T]o qualify as an original source, a relator does not have to have personal knowledge of all elements of a cause of action ... A false claim consists of a representation contrary to fact, made knowingly or recklessly. If the relator has direct knowledge of the true state of the facts, it can be an original source even though its knowledge of the misrepresentation is not first-hand." *Minnesota Assoc. of Nurse Anesthetists*, 276 F.3d at 1050; *see also United States ex rel. Nelson v. Biolink Partners*, 2006 U.S. Dist. LEXIS 21730, 04CV3139 (D. Neb. April 4, 2006).

In this case, the Relator has direct and independent knowledge of the true state of facts, namely that the Ventak PRIZM 2 DR 1861 defibrillators manufactured after April 2002 were defective and potentially deadly and that the Defendants were representing such devices to be free from defects. Relator has such direct and independent knowledge because on August 27, 2002, a Ventak PRIZM 2 DR 1861 defibrillator was implanted in his chest. (*See* Amended Complaint, ¶ 65). That device was manufactured by Defendants on June 13, 2002.

(*See* Amended Complaint, ¶ 65). That device malfunctioned, for the first time, on December 2, 2002, when it incorrectly read the Relator's heart rate and delivered seven (7!) unnecessary and potentially deadly 750 volt shocks to his heart. (*See* Amended Complaint, ¶¶ 66-67). The device malfunctioned for a second time in 2003, when it again "storm shocked" Relator's heart and caused him to fall down a flight of stairs. (*See* Amended Complaint, ¶ 69). Relator's attempts to have the lethally defective device replaced were initially thwarted by Defendants' salesman, James Davis, who told Relator's doctor that the device had not been recalled and was not defective, and that insurance would not cover the procedure to replace the device. (*See* Amended Complaint, ¶¶ 71-74).

Additionally, Relator communicated directly with a representative of the Defendants, Daniel J. Tich (Manager, Product Performance Communications, Reliability Assurance for Guidant Corporation), regarding Ventak PRIZM 2 DR 1861 defibrillators manufactured after April 2002, including the one implanted in him, and the representations made by Defendants concerning the safety of the device and changes that were made to remedy problems in the devices manufactured before April 2002. (*See* Amended Complaint, ¶¶ 82-97). While these representations were made after the claims to Medicare and the Veteran's Administration, Relator believes that these types of false representations are illustrative of the types of false representations that had been made by various

Guidant employees in 2002 and beyond in connection with the claims submitted to the Veterans Administration and Medicare. Clearly, these statements represented Guidant's official company position, and there is nothing in this record to indicate that this position changed in any way from the time of the false claims alleged in the Amended Complaint, until these very same claims were made to Relator directly.

Thus, Relator is not some random "disinterested outsider" off the street who obtained "secondhand knowledge of wrongdoing" by "simply stumbling across an interesting court file." Relator's information and experience is NOT derived from any prior litigation, nor is there any "intervening agency" from which Relator derived his information. Relator intimately "saw with his own eyes" – and felt in his own chest – the results of the fraud perpetrated by the Defendants. Moreover, Relator presented all of his personal information, as well as additional information supporting his personal experience and knowledge, to the FDA prior to commencing this, or any other legal action, against the Defendants. (*See* Amended Complaint, ¶¶ 88, 98-102).

This case presents circumstances similar to those in *United States ex rel. Nelson v. Biolink Partners*, *supra*, 2006 U.S. Dist. LEXIS 21730. In *Nelson*, the relator asserted that he was the owner, inventor, and holder of a patent on a device/process that completed rapid analysis of human blood or DNA. The relator

and his company worked for a time with the defendants in a partnership or joint venture arrangement to develop the scientific apparatus. The relationship ended in the fall of 2001, when the relator learned that defendants were claiming to be a co-author of patent documents pertaining to the device. The relator notified the National Institutes of Health ("NIH"), a division of the U.S. Department of Health and Human Services, that defendant was presenting false information to the NIH. The relator thereafter filed an FCA action alleging that defendants violated the FCA because they received federal grant funds from various federal government agencies based on false claims or fraudulent information, namely drawings, plans, schematics, and other documents claiming that various intellectual property was their own, and falsely represented that relator's employees were working for defendants, thereby obtaining grant funds.

The defendant argued that the relator obtained his knowledge of the alleged fraud from his review of NIH documents, and that he did not have firsthand knowledge of what defendants did or did not do. The realtor contended that he did have firsthand knowledge that he was the owner and inventor of the device; that he held a patent on the machine, its software and its working processes; that he had prepared certain drawings, plans, schematics, and other documents regarding the invention; and that his company employed certain employees. Citing *Minnesota Assoc. of Nurse Anesthetists*, the court held that "to qualify as an original source, a

relator does not have to have personal knowledge of all elements of a cause of action" and that "if the relator has direct knowledge of the true state of the facts, it can be an original source even though its knowledge of the misrepresentation is not first-hand." The court thus held that the relator's direct and independent knowledge of the "true state of facts" referenced above was sufficient to make him "an original source" of the FCA allegations.

Additionally, the court held that the relator's confirmation or corroboration of his suspicions by reviewing NIH documents did not preclude him from being an original source: "The fact that [relator] reviewed NIH documents, and allegedly confirmed his suspicions of fraud when reading the content of the grant applications, does not preclude him from being an 'original source' as defined in 31 U.S.C. § 3730(e)(4)(B)."

Here, as discussed above and as determined in *Nelson*, Relator has direct and independent knowledge of the true state of facts based on his personal experiences. The fact that Relator also conducted his own independent investigation and collected additional records and reports corroborating his own personal experience and further demonstrating the Defendants' misrepresentations does not preclude him from being an original source of the allegations supporting this FCA claims.

The cases cited and relied upon by Defendants only further demonstrate the distinction between the Relator in this case, who is "an original source," and the type of relator who does not qualify as an original source.

In *United States ex rel. Kinney v. Stoltz*, 327 F.3d 671 (8th Cir. 2003), the relator was a paramedic at the Hennepin County Medical Center ("HCMC"). He commenced an FCA action alleging that the defendants, four HCMC employees, falsely certified that all ambulance services it provided were medically necessary, thereby defrauding Medicare for ambulance runs that would not have otherwise been paid for because they were not "medically necessary." Interestingly, the relator had previously filed a substantially similar FCA ("Kinney I") directly against HCMC and the Hennepin Faculty Associates ("HFA"), i.e. the doctors at the HCMC. During the course of Kinney I, the relator conducted depositions. Kinney I was dismissed on summary judgment on various substantive grounds. The relator did not appeal that dismissal, but rather commenced a second FCA claim against the HCMC employees (Kinney II). It was during those depositions in Kinney I that the relator discovered the potential wrongdoing of the defendants in Kinney II. The court specifically noted: "Prior to the depositions, [relator] never indicated that he knew of [the Kinney II defendants] existence, or about any alleged misdeeds committed by them." 327 F.3d at 672. Thus, the court held that

the relator did not have direct knowledge, and thus was not "an original source" because:

> [Relator] alleged in [Kinney I] that [HCMC and HFA] were responsible for the fraud. He made no mention of the [HCMC employees] and there is no evidence in the [Kinney I] record that he was aware of the role played by [the HCMC employee defendants in Kinney II] until after discovery [in Kinney I]. If [relator] had possessed direct knowledge of the asserted fraud in [Kinney II], he was obliged to identify them in his initial complaint.

Id. at 675. In short, *Kinney* does not represent the broad holding that Defendants make it out to be. The decision in *Kinney* does represent the typical parasitic claim wherein the relator was attempting to use information derived from litigation to bring an FCA claim – after his initial FCA claim was dismissed on substantive grounds. That case simply has no bearing on the facts or circumstances of this action.

United States ex rel. Barth v. Ridgedale Elec., 44 F.3d 699 (8th Cir. 1995), also heavily relied on by the Defendants, is similarly distinguishable from the present case. In *Barth*, the relators (an individual and a union) asserted an FCA claim alleging that defendants violated the act by submitting false certifications of contract compliance and fraudulent payroll reports to the government in order to conceal the fact that the defendants had failed to pay their employees the prevailing wages required by the Davis-Bacon Act for their work on a federally-funded electrical construction project. The individual relator was an employee of one of

the defendants who had worked on the project. His employer prevailed upon him to submit false time cards to indicate that he worked in a different capacity than his actual employment. Additionally, while the project was in progress, a business representative of the Union visited the job site on a number of occasions and observed the nature of the work performed by defendant's employees. He also met with employees in an attempt to organize them, during which he discussed the wages they had received on the project. Subsequently, the union representative obtained copies of the payroll reports the defendant had submitted on the project. From these reports and his discussions with employees, the union representative formed a suspicion that defendant had falsely characterized its employees on the payroll reports. He again spoke with employees to confirm his suspicions. He then relayed the information he gathered to a HUD investigator. Shortly thereafter, the HUD investigator met with the individual relator, who confirmed that he had been employed in a different capacity that set forth on the time sheets.

The court dismissed the FCA claim based on the public disclosure bar. The issue in the case was whether the relators qualified as "an original source." 44 F.3d at 703. The court held that the union did not qualify as an original source because the union representative did not have direct knowledge relating to the allegations. The court noted that the union representative's information was obtained through intermediary sources, including (1) his visits to the project job

site and his observations of individuals doing work; (2) copies of publicly-filed payroll records indicating these employees were not being paid the wages matching the job description they were performing; and (3) his interviews with employees. *Id.* at 703-04. The court noted that the union representative "was, in effect, simply gathering information on behalf of the Union...[and] as such, he was a recipient of information and not a direct source." *Id.* at 704. While the court held that the individual relator did have direct knowledge of allegations, his claim was dismissed because he failed to "voluntarily disclose" his knowledge to the government – he only disclosed information after the HUD agent came to him based on the union's investigation. *Id.*

Unlike the individual relator in *Barth*, it is undisputed that the Relator here voluntarily provided his information and knowledge to the FDA prior to commencing this action. Further, as detailed above, the Relator has direct knowledge of the Defendants' wrongdoing based on his own intimate, personal experience. The Relator did not have to go to anyone else to learn that the Guidant devices were defective. He knew this from his own experience. Relator is not, like the Union in *Barth*, a "secondhand informant" whose allegations are based solely on collateral research and information.

Lastly, *United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148 (2d Cir. 1993), also relied on by Defendants, is

distinguishable from this case and serves to further demonstrate the difference between a "parasitic claim" and the present claim. In *Kreindler*, the relator was a law firm that had represented the widow of a United States warrant officer in a wrongful death action arising from a Black Hawk helicopter crash. The relator's FCA claim was based on the information disclosed during discovery in the underlying wrongful death action and, as such, the law firm was not an original source of the information. The law firm did not have any personal knowledge or personal experience with Black Hawk helicopters, but rather took what it learned from the underlying lawsuit and reframed it as an FCA claim.

Relator is not simply taking other people's knowledge and experience to create a claim. Relator has personal knowledge of and experience with the device that is the subject of his FCA claim. Moreover, attempting to analogize *Kreindler* to this case on the basis that Relator had a prior underlying personal lawsuit against the Defendants completely misses the mark. *See Cox, supra*, 2010 U.S. Dist. LEXIS 1608 (D. NE. 2010) ("Whether the public disclosure bar applies to deprive the court of subject matter jurisdiction in this case therefore depends on whether [the relator] was an 'original source' of the allegations made in the prior case. Considering that [the relator] filed both lawsuits, this would seem to be a foregone conclusion").

Accordingly, for the reasons set forth herein, this Court has subject matter jurisdiction over Relator's FCA claims because Relator is "an original source" of the allegations set forth in the Amended Complaint.

POINT II

RELATOR HAS ADEQUATELY PLEADED HIS FRAUD ALLEGATIONS WITH THE REQUISITE PARTICULARITY REQUIRED BY RULE 9 (B) APPLICABLE TO FCA CLAIMS

a. The Amended Complaint Provides Sufficient Notice to Guidant

"A Federal Claims Act violation claim requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake." *Unterschuetz v. In Home Personal Care, Inc., et al.*, 2008 U.S. Dist. LEXIS 81914 (D. of Minnesota 2008) citing Fed. R. Civ. P. 9 (b). Rule 9 (b)'s "particularity requirement demands a higher degree of notice than that required for other claims," and "is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations." *Joshi v. St. Luke's Hospital, Inc., et al.*, 441 F.3d 552 (8th Cir. 2006) *citing United States ex rel. Costner v. URS Consultants, Inc.*, 317 F.3d 883, 888 (8th Cir. 2003). In this regard, "the sufficiency of a pleading must largely depend upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *See Payne v. United States*, 247 F.2d 481,486

(8th Cir. 1957). The requirement of Rule 9(b) must be read in conjunction with Fed.R.Civ.P 8(a), which provides for "a short and plain statement of the claim" for relief. Thus, while a Relator must allege the circumstances of the fraud, he is not required to plead all of the evidence or facts supporting it. *United States ex rel. v. Parke-Davis, Div. of Warner Lambert Co.*, 147 F.Supp.2d 39, 46-47 (D.Mass. June 25, 2001) (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1298, at 625-26 (2nd ed. 1990) (Rule 9 (b) does not require plaintiff to resort to "fact pleading"); *see also United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 U.S. Dist. LEXIS 22449 (E.D. Mo. Eastern Div April 21, 2006).

Here, nowhere in their motion papers do defendants claim that they do not have sufficient notice of Mr. Allen's claims as set forth in the Amended Complaint. Defendants know that the device involved is the PRIZM 2 DR 1861 defibrillator; they know to whom the claims for the PRIZM 2 DR 1861 defibrillators were made; and they know what representations they made or failed to make regarding the efficacy of the PRIZM 2 DR 1861 defibrillators. *See* Amended Complaint ¶¶1-8, 36-37, 63-64, 110-115, 130-136. Thus, it must be concluded that the Amended Complaint, herein, gives Guidant sufficient notice to respond to the allegations. *See Payne*, 247 F.2d at 486.

b. The Amended Complaint Satisfies The Particularity Requirement

Furthermore, to satisfy the particularity requirement, the complaint must plead such facts as time, place, and content of the defendant's false representations as well as details including when the acts occurred, who engaged in them, and what was obtained as a result. *See Joshi*, 441 F.3d at 556 (*citations omitted*). Put another way, the complaint must identify the "who, what, where, when and how" of the alleged fraud. *Id.* (*citations omitted*).

However, when a case involves a "complex scheme of fraud over an extended period of time," the particularity requirement should be relaxed. *Alakser et al. v. Centracare Health System, Inc. et al.*, 2002 U.S. Dist. LEXIS 10180 (D. Minnesota, 2002); *see also Wilkins ex rel. United States v. Hampton*, 885 F.Supp. 1055, 1061 (S.D. Ohio 1995) (allowing qui tam relator to plead certain facts on information and belief). In fact, where the facts constituting the fraud are peculiarly within the opposing party's knowledge, such allegations may be pleaded on information and belief. *See Drobnak et al., v. Andersen Corp. et al.*, 561 F.3d 778 (8th Cir. 2009) *citing Fla. State Bd. Of Admin. V. Green Tree Fin. Corp.*, 270 F.3d 645 (8th Cir. 2001). "Rule 9 (b) is deemed satisfied if the allegations are accompanied by a statement of facts on which the belief is founded." *Id. citing Parnes v. Gateway 2000, Inc.*, 122 F.3d 539 (8th Cir. 1997).

In *Luckey v. Baxter Health Care Corp.*, 1996 U.S. Dist. LEXIS 6252 (N.D. Ill. 1996), an employee claimed that the employer knowingly misrepresented to the United States that plasma products the employer sold to it had been adequately and effectively tested for the presence of viral contaminants, when in fact, they had not.

The Court in *Luckey* found that the amended complaint sufficiently alleged fraud for the purpose of Rule 9(b) giving the defendant sufficient notice to prepare a defense against the claim. *See id.* at *25. The Court concluded that the allegations in the complaint did not vaguely refer to unidentifiable transactions and misrepresentations. *Id.* Rather the Court held:

> ... Luckey alleges that Baxter made misrepresentations each time it sold plasma products to the government, and that the content of the misrepresentations guaranteed that the plasma was adequately and effectively tested for viral contaminants. (citations omitted). Moreover, Luckey details the grounds for her claim that these guarantees were fraudulent. The amended complaint pleads that Baxter knew that the plasma had not been adequately and effectively tested (citations omitted), and alleges facts regarding plasma testing and processing, Baxter policies, and violations of specific Baxter protocols, and government regulations. (citations omitted).

The Court further accepted the plaintiff's assertion that details, such as the identity of the individual who communicated the guarantees, the precise time, place and method of each communication were in the sole possession of the defendant prior to discovery. *Id.* at *26.

Additionally, in *Yannacopolous v. General Dynamics, et al.*, 315 F.Supp.2d 939 (N.D. Ill. 2004), Relator-plaintiff, a former employee, alleged defendants, his former employer and its successor, violated the False Claims Act by submitting false claims in connection with F-16 fighter aircraft sales to Greece. Defendants, in separate motions, moved to dismiss. Among other things, defendants argued that the employee failed to plead fraud with particularity as required by Rule 9(b).

In particular, the defendants argued that the relator failed to plead the "who, what, when, where and how" of the alleged fraudulent claims. The Court disagreed. Regarding the "who" element, the Court determined that these details were in the exclusive possession of defendants and the Relator need not allege them under Rule 9(b). *Id.* at 945 (citations omitted). Regarding the "what" element, the Court determined that the relator sufficiently pleaded numerous allegations of "what" defendants did to defraud the United States (i.e. overbilling a client for products and services never delivered may constituted fraudulent activity). *Id.* Relative to the "when" element, the Court found that the relator pleaded specific dates regarding contract submissions and modifications as well as specific timeframes during which defendants submitted allegedly fraudulent quarterly invoices for payments. Anything more specific was unnecessary. *Id.* Regarding the "where" element, the relator alleged the false claims were made in essentially three places, General Dynamic's various facilities, Greek Government

facilities and U.S. Government facilities. In this regard, the Court concluded that "[a]ny greater specificity in the complaint would undermine the purpose of Fed.R.Civ.P. 8 notice pleading, which must be read in conjunction with Rule 9(b)." *Id.* at 946.

Here, unlike the Relators in *Luckey* and *Yannacopolous,* who at one point were employees of the defendant named in the *qui tam* actions, Mr. Allen was not a an employee of Guidant but rather, he was a patient with a defective PRIZM 2 DR 1861 defibrillator that malfunctioned on two occasions. *See* Amended Complaint ¶¶ 66-69.

Moreover, this court should adopt the same standard used by the courts in both *Luckey* and *Yannacopolous*, in terms of identifying the "who" element which should be applied here. Specifically, this court should find that the details of the identity of the specific person or persons employed by Guidant who (1) failed to disclose the defective and dangerous conditions of the PRIZM 2 DR 1861 defibrillator (Amended Complaint ¶111,117); (2) represented that the PRIZM 1861 defibrillators were free of any known defects (Am. Complaint ¶111) (3) failed to obtain and make FDA submissions for changes to the device (Am. Complaint ¶112,121) are in the exclusive possession of Guidant and therefore unable to be obtained by Mr. Allen prior to any meaningful discovery. *See generally, Luckey, supra* at *26*; Yannacopolous, supra* at 945.

In this same regard, the Court should further find that Mr. Allen satisfied the requirements of Rule 9(b) relative to the "who" element because it would be impossible for Mr. Allen to identify a specific employee of Guidant where no disclosure was made to the FDA regarding the defective condition of the Prizm devices at issue in this FCA. *See*, *Lockhart v. General Dynamics*, 529 F.Supp.2d 1335 (N.D.. Fla. 2007) (holding "[o]ne cannot give the date of an event that did not happen, or identify the person who made a disclosure that was not made"). Guidant should, therefore, not be allowed to use Rule 9(b) as a sword where it had a duty to disclose the defective and dangerous conditions of the Prizm devices, but failed to do so. A dismissal of the Amended Complaint would serve only to enable Guidant's fraudulent conduct.

Furthermore, Mr. Allen has fully set forth the "what" element in the Amended Complaint. Mr. Allen specifically alleges that Guidant knew in February 2002 that there was a potential for electrical short circuiting in the Prizm devices (Amended Complaint ¶ 108 (a)); that Guidant concealed the defects from the FDA (Amended Complaint ¶117); that Guidant represented to Medicare and the Veteran's Administration that the Prizm devices were free of known defects (Am. Complaint ¶111); that Guidant failed to obtain and make FDA submissions for several changes and additions to the Prizm devices (Am. Complaint ¶¶38-44, 121-123; that Guidant failed to make changes to the Prizm devices manufactured

between April 16, 2002 through November 13, 2002 that it claimed it made (Am. Complaint ¶45-46); and that Guidant used an adhesive/insulation that was not FDA approved in the Prizm devices, which caused the devices to fail (Am. Complaint ¶49-57). These allegations set forth in the Amended Complaint demonstrate the "what" element, i.e. that Guidant failed to communicate and disclose defects to the FDA where it had a duty to do so. To require more of Mr. Allen would, in effect, force him to plead all of the evidence or facts supporting his claim which is not required. *See United States ex rel. v. Parke-Davis, Div. of Warner Lambert Co., supra.*

Consequently, the fraudulent representations made by Guidant relative to the Prizm devices and Guidant's failure to disclose to the FDA and others purchasing these devices the defective and dangerous conditions associated with the Prizm devices that were manufactured from April 16, 2002 through November 13, 2002 and from November 13, 2002 through October 5, 2007 caused hospitals, physicians and other providers to submit and receive payment for false and fraudulent Medicare/Veteran's Administration claims. (Amended Complaint ¶117-118). In particular, Mr. Allen identifies the following devices that were sold and implanted for which the Veterans Administration paid claims: serial number 230863 implanted on September 13, 2002 in the San Antonio Veterans Administration Hospital; serial number 240118 implanted on October 8, 2002 in

the Tampa Veterans Administration Hospital; serial number 239693 implanted on January 13, 2003 in the Denver Veterans Administration Hospital; serial number 242256 implanted on January 16, 2003 in the Decatur Veterans Administration Hospital; and serial number 234219 implanted on January 23, 2003 at the Portland Veterans Administration Hospital. (Amended Complaint ¶127).

Thus, looking at the four corners of the Amended Complaint, Mr. Allen has satisfied his burden of demonstrating the particularity requirement of showing the "who, what, where, when and how" of the alleged fraud. *See Joshi*, *supra* at 556. Accordingly, Guidant's motion seeking to dismiss Mr. Allen's claims pursuant to Rule 9(b) should in all respects be denied.

c. The Particularity Requirement Should be Relaxed

In light of the complexity of Guidant's fraudulent scheme involving Prizm devices manufactured between April 16, 2002 and November 13, 2002 and from November 13, 2002 through October 5, 2007, the particularity requirement should be relaxed. *Alakser et al. v. Centracare Health System, Inc. et al.*, 2002 U.S. Dist. LEXIS 10180 (D. Minnesota, 2002). The case at bar involves an elaborate scheme by Guidant which knew of the dangerous defects involving the Prizm devices for years but concealed these defects and failed to disclose them to the FDA despite its

duty to do so.[1] Rather, Guidant continued to represent that the Prizm devices were free from known defects. (*See* Am. Complaint at ¶110). Thus, the complexity of Guidant's deceptive scheme of failing to disclose defects with Prizm devices warrants a determination by this Court to relax the particularity requirements. *See, id.*

Mr. Allen's Complaint pleads fraud with the particularity required of Rule 9(b). Accordingly, Guidant's motion seeking to dismiss the Amended Complaint pursuant to Rule 9 (b) must be dismissed.

POINT III

THE UNITED STATES' COMPLAINT DID NOT SUPERSEDE RELATOR'S COMPLAINT

Defendant's argument that the Government's Complaint in Intervention supersedes the Relator's Amended Complaint fails for several reasons. First, nothing in the FCA supports defendants' argument that the mere filing of a complaint by the Government supersedes Relator's Amended Complaint. In fact, the FCA makes clear that even if the Government intervenes in a pending FCA action, the private relator still has a right to continue as a party to the action, subject to several statutory limitations. *See* 31 U.S.C.A. § 3730(c)(2)(A). The first

[1] In 2002, Guidant concluded there was a potential for electrical short circuiting in the PRIZM 1861 defibrillator affecting its efficiency and safety. In 2005, Guidant admitted that the potential for electrical short circuiting rendered the PRIZM 1861 defibrillator defective and recalled all such devices manufactured before April 16, 2002. *See* Amended Complaint at ¶108 (a) and (b).

three limitations set forth in the FCA are not applicable here. *See* 31 U.S.C.A. §§§ 3730(c)(2)(A-C). Thus, the only way the Relator's role could be limited in this case is "[u]pon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense." *See id.* at § 3730(c)(2)(D). However, Defendants have failed to allege that the Relator has initiated the action for purposes of harassment or would cause the Defendants undue burden or expense.

Second, the case law relied upon by Defendants does not support their position that the Governments Complaint in Intervention supersedes Relator's Amended Complaint. As an initial matter, the case of *United States ex re. Alsaker v. Centra Health Sys., Inc.*, 2002 U.S. Dist LEXIS 10180, at *6 n.2 (D. Minn. June 5, 2002), did not involve a situation, as in this case, where the United States and the Relator seek to pursue different claims. As the Court is aware, the Governments Complaint in Intervention does not adopt all of Relator's claims in the Amended Complaint. Thus, the Government's Complaint in Intervention was not intended to "write over" an earlier complaint filed by the same party. Thus, the general rule that an amended complaint nullifies an earlier complaint filed by the same party does not apply to Relator's Amended Complaint.

Nor is *United States ex rel. Prawer & Co. v. Fleet Bank of Maine*, 1995 U.S. Dist LEXIS 16095 (D. Me. 1995), helpful to Defendants' argument. Defendants rely on *Prawer* for the proposition that "once the government filed its Complaint in Intervention, Relator was required to take steps to either sever those additional claims he wished to pursue from the United States' complaint, or file his own new complaint on those claims not adopted by the government." (*See* Defendants' Memorandum of Law, p. 17.) However, the *Prawer* Court did not require severance, but rather noted a relator's claims "may" be severed from an action in which the United States has intervened when the relator sues more defendants than the United States names in its complaint in intervention:

> For these reasons, I conclude that the proper construction of the False Claims Act is as follows. When a private relator or relators sues more than one defendant, and the Government limits its intervention to fewer than all the defendants, the action ***may*** be severed into two parts: the Government's claims against one or more defendants; and the private relator's claims against one or more defendants

United States ex rel. Prawer & Co., 1995 U.S. Dist. LEXIS 16095 at *10-11 (emphasis added).

Approximately one year later, the relator in *Prawer* filed a motion to consolidate its severed claims with the United States' action. *United States ex rel. S. Prawer & Co. v. Verrill & Dana*, 1996 U.S. Dist. LEXIS 10029 (D. Me. June 13, 1996). The court did not rule on the motion to consolidate. However, it held

that "the private relators' earlier request for severance does not prevent their...request for consolidation now." *Id.* at *9-10. Thus, the court in *Prawer* recognized that even if a relator's complaint was not perfectly aligned with the United States' complaint in intervention, the two complaints could be prosecuted in the same action. In sum, *Prawer* does not support defendants' argument. It actually supports Relator's right to prosecute his Amended Complaint in this action.

CONCLUSION

For all of the reasons set forth herein, Relator respectfully requests an order denying defendants' motion to dismiss in its entirety.

DATED: December 21, 2011

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